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AUG 18 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Semple et al.

Application No.: 09/654,373

Filed: 9/1/2000

Title: Novel Small Multilamellar Vesicle Structures

Attorney Docket No.: INEX.P-007

Customer No.: 021121

Group Art Unit: 1651

Examiner: David Naff

Confirmation No: 5857

OFFICIAL

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

In response to the Office Action of March 23, 2004, please amend this application as follows:

**Amendments to the specification** are shown beginning on Page 2 of this paper.

**Amendment to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

I hereby certify that this paper and any attachments named herein are transmitted to the United States Patent and Trademark Office, Fax number: 703-872-9306 on August 18, 2004.

Marina T. Larson  
Marina T. Larson, PTO Reg. No. 32,038

August 18, 2004  
Date of Signature

Page 1

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DIPE/JCW/S

Appln No.: 09/654,373

Amendment Dated: August 18, 2004

Reply to Office Action of March 23, 2004

Page 10 please amend the paragraph starting on line 21 as follows:

The SMV are formed from a lipid component and a ODN. The lipid component comprises 20-30 mol %, and more preferably 20-25% of an ionizable amino lipid. The ionizable lipid is selected such that raising the pH surrounding the small multilamellar vesicles to a pH of around 7.5 results in the release ~~are substantially free of external, non-encapsulated oligodeoxynucleotides at physiological pH. The term "physiological pH" refers to pH levels conventionally encountered in serum or blood. In general, this will be in the range of pH 7.2 to 7.5. Ionizable lipids have a pKa such that they are substantially neutral at this pH, i.e., a pKa of about 4 to 7 in the case of an amino lipid.~~ A preferred ionizable amino lipid is DODAP. Other ionizable lipids which could be used include DODMA.